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Via e-mail and electronic submission

Re: Comments on Proposed Amendment to Sections 25821(a) and (c), Level of Exposure to Chemicals Causing Reproductive Toxicity: Calculating Intake by the Average Consumer of a Product

Dear Ms. Vela,

As You Sow submits the following comments on OEHHA's proposed amendments to Title 27, California Code of Regulations, Article 8, Sections 25821(a) and (c), Level of Exposure to Chemicals Causing Reproductive Toxicity.

OEHHA has proposed amendments to Section 25821(a) and (c) of its regulations implementing Proposition 65[1]. In its Initial Statement of Reasons (ISOR), OEHHA explains that "[t]he purpose of the proposed amendments is to clarify how a business should calculate exposures to listed reproductive toxicants" that are not explained by the existing regulatory provision. (ISOR, p. 4).

As You Sow applauds OEHHA's efforts to clarify and improve its existing regulation. As detailed below, while we think that the proposed amendments are a step in the right direction, additional clarifications are required to ensure that the calculation of exposures to listed reproductive toxicants under Section 25821 comply with Proposition 65's objective of protecting individual consumers from exposure to toxic chemicals.

Discussion

I. OEHHA's Proposed Amendment to Section 25821(a)

Section 25821(a) of OEHHA's implementing regulations interprets the phrase "level in question" in Proposition 65 as "the chemical concentration of a listed chemical for the exposure in question." (27 CCR § 25821(a); Health & Safety Code § 25249.10(c)). OEHHA proposes the

[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 *et seq.* (referred to herein as "Proposition 65" or "the Act").

following addition to Section 25821(a) to clarify how to calculate the "level in question" of a chemical in food products.

> For purposes of this section, where a business presents evidence for the "level in question" of a listed chemical in food products based on the average of multiple samples of that food, the level in question may not be calculated by averaging the concentration of the chemical in food products from different manufacturers or producers, or that were manufactured in different manufacturing facilities from the product at issue.

(OEHHA, Proposed Regulatory Text).

As You Sow supports OEHHA's proposed additional language making clear that the "level in question" should not be based on the average concentrations of a listed chemical in food products that were made by different manufacturers or producers, or that were from different facilities. As OEHHA correctly notes, under Proposition 65, "the estimated concentration of a reproductive toxicant in a food product should reflect the exposure that an individual experiences from the particular food product when consumed." (ISOR, p. 5). Averaging concentrations of chemicals in food products made by different manufacturers/producers or from different facilities may result in concentration levels of chemicals that are lower than the actual level an individual would be exposed to from consuming a particular food product. (*See* ISOR at pp. 4-5). The proposed additional language ensures that the calculation of "level in question" more closely represents actual concentrations of chemicals in a food item, and incentivizes businesses to take measures to reduce and eliminate consumer exposure to potential toxicants in food products in furtherance of the purposes of Proposition 65.

While we support the proposed amendment, we believe the following additional clarifications are necessary to ensure that the calculation of the "level in question" sufficiently protects Californians under Proposition 65:

1. **OEHHA Should Make Clear that Averaging of the "Level in Question" Is Not Always Appropriate.**

In addition to making clear that averaging chemical concentrations across products or manufacturers is inappropriate, OEHHA must also make clear that food products that are produced at different times, or that have significantly different levels of listed chemicals, due to for example, having been grown or produced with ingredients grown from different locations, cannot be averaged together in determining the "level in question." It is common in today's marketplace for manufacturers to use ingredients from different sources, or alter compositions of their food products between batches, which can result in dramatically different levels of chemical concentrations between batches of the same food product. In many instances, the manufacturer/producer uses certain ingredients that contain higher levels of listed chemicals than other ingredients of the same kind, and should therefore be required to provide a warning for such exposures.

OEHHA itself acknowledges that "the amounts of listed chemicals in food products can vary significantly based on when and where the food was grown, processed or packaged," (ISOR,

pp. 4-5), but the current proposed amendment does not directly address these variabilities. If a manufacturer/producer is using ingredients that have significantly higher concentrations of a chemical produced during a certain season or production run, or because it was grown in areas with high levels of chemicals in the soil, it should not be able to bypass its legal duty to provide a warning simply by averaging the "level in question" with products produced at different times. Similarly, if ingredients from a particular locality likely contain concentrations of a listed chemical exceeding the regulatory threshold, then warning is required under Proposition 65. Accordingly, OEHHA should modify the existing proposed amendment to prohibit averaging the "level in question" across products produced over different time periods, production runs, or locations.

II. OEHHA's Proposed Amendment to Section 25821(c)(2)

Section 25821(c)(2) currently provides: "For exposure to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population." OEHHA is proposing to amend this section by adding the sentence: "This rate of intake or exposure is calculated as the arithmetic mean of the rate of intake or exposure for users of the product." OEHHA points to Proposition 65 defendants' use of the geometric mean to food consumption data in calculating the rate of intake, such as in *Environmental Law Foundation v Beechnut Nutrition Corp. et al.*, (2015) 235 Cal.App.4th 307, and explains that the proposed amendment clarifies the arithmetic mean should be used when characterizing an average consumer's intake. (ISOR, p. 4).

1. OEHHA Should Make Clear That It Is Articulating a Position That When Averaging Occurs, the Arithmetic Mean Should Be Applied.

We agree with OEHHA that the use of the geometric mean is inappropriate and that the Arithmetic Mean better protects consumers. However, as written, the proposed amendment is overbroad. We propose that the clearest way to address this issue is to provide that "Where averaging is appropriate, the rate of intake or exposure is calculated as the arithmetic mean of the rate of intake or exposure for users of the product."

2. OEHHA Should Make Clear That the Calculation of the Rate of Intake or Exposure Must Account for Distinct Average User Groups.

As written, the proposed amendment can be interpreted to suggest that all average users of a product are identical, and should be grouped together for purposes of deriving a single arithmetic mean for rate of intake or exposure. Such an interpretation is contrary to Proposition 65's protective purpose. Indeed, many products have distinct user groups that are exposed to very different levels of chemicals in the products due to their unique use patterns. For example, while many consumers consume protein/nutritional shakes as part of an active lifestyle, there are also subpopulations that, due to health conditions, rely on protein/nutritional shakes as meals to obtain necessary nutrients in their diets. In such a case, taking a single arithmetic mean of all average users of protein/nutritional shakes as the rate of intake for all average users would not sufficiently protect those who consume protein/nutritional shakes as meal replacements, in

violation of Proposition 65's requirement to provide warning to "any individual." (Health & Safety Code 25249.6). This is only one instance of distinct users of a product that must be considered. Proposition 65's goal of ensuring protection against the full range of exposures experienced by Californians would require treating user groups with distinct user patterns separately in assessing exposure. OEHHA should amend Section 25821 to make clear that the rate of intake must be considered for each distinct use pattern.

CONCLUSION

As discussed above, *As You Sow* believes that OEHHA's proposed amendments are a step in the right direction. Additional clarifications, as outlined above, will further enhance OEHHA's intent to ensure that Section 25821 is consistent with the purposes of Proposition 65.

Thank you for providing this opportunity to comment on these important issues.

Sincerely,

Sylvia Wu
Staff Attorney
As You Sow